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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/600,584	06/19/2003	Robert W. Blakesley	55670DIV(45858)	5497
21874 7590 01/24/2008 EDWARDS ANGELL PALMER & DODGE LLP P.O. BOX 55874 BOSTON, MA 02205			EXAMINER BABIC, CHRISTOPHER M	
			ART UNIT 1637	PAPER NUMBER
			MAIL DATE 01/24/2008	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

# Office Action Summary

Application No.

10/600,584

Applicant(s)

BLAKESLEY ET AL.

Examiner

Christopher M. Babic

Art Unit

1637

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 12 October 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 26, 27 and 33-48 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 26, 27, and 33-48 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Examiner of Record***

As an initial matter, it is noted that the Examiner of record has been changed from John Brusca, Art Unit 1631, to Christopher M. Babic, Art Unit 1637.

### ***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on October 12, 2007 has been entered. Claim(s) 26, 27, and 33-48 are pending.

### ***Withdrawn Claim Rejections - 35 USC § 112 - Indefiniteness***

The rejection of claim(s) 40-42 has been withdrawn in view of Applicant's amendments.

### ***Claim Rejections - 35 USC § 102 - New Grounds***

The following rejection(s) is/are made in view of previously unconsidered prior art.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

**Claim(s) 26, 27, 33, 34, 37, 41, and 42 are rejected under 35 U.S.C. 102(b) as being anticipated by Fujishiro (JP 07-250681; 10 March 1995; translation provided by JPO @ <http://www.ipdl.inpit.go.jp/>).**

With regard to claim(s) 26, 27, 37, 41, and 42, Fujishiro teaches methods for the isolation of plasmid DNA from bacterial cells (abstract; pg. 1 of translation, for example). Specifically, Fujishiro teaches a method comprising: a) contacting a matrix or solid medium with a sample comprising a host cell or virus containing said vector or vectors ([0007]-[0011] of translation, *Fujishiro teaches the growing of plasmid containing E. coli., application of the E. coli to a solid medium comprising a "trap filter," and the lysis of the E. coli, for example*); and b) isolating all or a portion of said vector or vectors from said medium ([0012]-[0013] of translation, *Fujishiro teaches the elution of plasmid DNA from the solid medium, for example*).

With regard to claim(s) 33 and 34, Fujishiro teaches polymeric and cellulose-based matrices [0016]-[0017], polyethylene, cellulose acetate, for example).

***Maintained Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

**Claims 26, 27, 33-39, 43-48 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rogers et al. ("Bacterial typing: storing and processing of stabilized reference bacteria for polymerase chain reaction without preparing DNA--an example of an automatable procedure" Anal Biochem. 1997 May 1;247(2):223-7) in view of Burgoyne (U.S. 5,496,562), and in view of Kahn et al. (Plasmid cloning vehicles derived from plasmids ColE1, F, R6K, and RK2" Methods Enzymol. 1979;68:268-80).**

The claims are drawn to a method of isolation of vectors from host cells by contacting the host cells with a solid medium. In some embodiments the solid medium protects the vector from degradation, is made of cellulose or a micromesh plastic, the host cells are in solution, and the solid medium comprises urate salt, a chelating agent, and an anionic detergent.

Rogers et al. shows in the abstract and throughout recovery of DNA from bacterial liquid cultures by application of the bacterial culture to FTA® blood storage medium. Figures 1 and 2 show positive results of PCR assay of bacterial DNA from FTA® media to which bacterial cultures were applied. Rogers et al. shows that the DNA is stable for at least 1.6 years after application to the FTA® media on page 226. Rogers et al. does not show use of bacteria comprising vectors, media comprising micromesh plastic, and Rogers et al. does not detail the composition of the chemicals in the FTA media. Rogers et al. states on page 223 that FTA® medium is described in Burgoyne (U.S. Patent No. 5,496,562).

Burgoyne shows the components of a solid medium for preserving DNA in columns 2-4, including use of a solid support such as cellulose or a micromesh of a synthetic plastic (column 2, lines 21-23), urate, an anionic detergent, and a chelating agent (column 2, lines 54-64 and column 3, lines 18-26). Burgoyne shows the application and storage of isolated plasmids on the solid medium in Example 2, columns 4-6. Burgoyne discloses application of plasmid pUC19 and recovery of approximately 100% of the applied plasmid from the solid matrix in column 6. Burgoyne claims a

method of application of generic DNA and recovery of the applied DNA from a solid matrix in at least claim 6.

Kahn et al. reviews plasmid cloning vectors, and shows that such vectors are replicated in bacteria in the abstract and throughout. Kahn et al. shows on page 268 that plasmid vectors are useful for cloning and maintenance of foreign DNA.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to modify the method of Rogers et al. by use of bacteria comprising vectors because Burgoyne shows that the solid media used by Rogers et al. can be used for long term storage and recovery of plasmids, and Kahn et al. shows that bacterial plasmid vectors are useful for cloning and maintenance of foreign DNA.

#### **Response to Arguments**

Applicant's arguments have been fully considered but they are not persuasive.

Applicant argues that, in contrast to the claimed invention, Rogers teaches PCR of genomic DNA in situ on FTA® medium, and Burgoyne teaches application of previously purified plasmid DNA to FTA® cards and the plastic coating of such cards. As noted previously in the Office Action dated May 1, 2007, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references (pg. 5).

Applicant further argues that a later filed patent application claiming an invention based on a desirable result (most inventions being desirable) is not tantamount to a motivation to combine unrelated references in hindsight. Also, Applicant argues that

nothing in either reference, either alone or in combination, suggests that combining the references would somehow manage to yield a method for storing or, as here, isolating plasmids present in cells. The examiner respectfully disagrees. First, in response to applicant's argument the references are unrelated, it has been held that a prior art reference must either be in the field of applicant's endeavor or, if not, then be reasonably pertinent to the particular problem with which the applicant was concerned, in order to be relied upon as a basis for rejection of the claimed invention. See *In re Oetiker*, 977 F.2d 1443, 24 USPQ2d 1443 (Fed. Cir. 1992). In this case, both references are concerned with the application of biological material to FTA® medium.

Furthermore, it appears that applicant is applying the "teaching, suggestion, or motivation test" too rigidly. It is noted that in *DyStar Textilfarben GmbH & Co. Deutschland KG v. C.H. Patrick Co.*, 80 USPQ2d 1641 (Fed. Cir. 2006), the court addressed the "teaching, suggestion, or motivation test" reciting the following,

"Our suggestion test is in actuality quite flexible and not only permits, but requires, consideration of common knowledge and common sense,...,Indeed, we have repeatedly held that an implicit motivation to combine exists not only when a suggestion may be gleaned from the prior art as a whole, but when the "improvement" is technology-independent and the combination of references results in a product or process that is more desirable, for example because it is stronger, cheaper, cleaner, faster, lighter, smaller, more durable, or more efficient. Because the desire to enhance commercial opportunities by improving a product or process is universal—and even common-sensical—we have held that there exists in these situations a motivation to combine prior art references **even absent** any hint of suggestion in the references themselves. In such situations, the proper question is whether the ordinary artisan possesses knowledge and skills rendering him capable of combining the prior art references,...,Persons of varying degrees of skill not only possess varying bases of knowledge, they also possess varying levels of imagination and ingenuity in the relevant field, particularly with respect to problem-solving abilities."



In the instant case, Rogers and Burgoyne demonstrate that bacterial DNA is stable within cultures stored on FTA® medium for significant periods of time. Furthermore, as was well known in the art at the time of invention, Kahn demonstrates that bacterial cells can carry plasmid vectors that are useful for cloning and maintenance of foreign DNA. Thus, as common sense would have dictated, a skilled artisan at the time of invention would have been motivated to utilize FTA® medium for long-term storage of plasmid vectors within bacterial cells.

Next, as understood by the examiner, applicant argues (as in the arguments dated February 14, 2007) that because of the inherently different properties of genomic DNA vs. plasmid DNA, as demonstrated by Old and Primrose, it could not have been assumed that plasmid DNA would elute from bacterial cultures on FTA® medium in the same manner as chromosomal DNA, i.e. the combination of references is invalid because there is no reasonable expectation of success, i.e. an operable invention. The examiner respectfully disagrees. Rogers clearly shows that FTA® medium ruptures bacterial cell walls such that PCR reagents can effectively amplify cellular DNA. Thus, it is clear that once applied to FTA® medium, bacterial cell walls are disrupted such that cellular DNA is liberated from the cell. Furthermore, Burgoyne clearly shows that pure plasmid DNA can be eluted from FTA® medium. Thus, it is clear that the circular structure of bacterial plasmid DNA does not interfere with or prevent elution from FTA® medium. Given these teachings, a skilled artisan would have a reasonable expectation of success when attempting to elute plasmid DNA from a bacterial culture on FTA®

medium. Applicant is reminded that obviousness does not require absolute predictability (see MPEP 2143.02, for example).

With respect to Hansen, the reference provides no evidence that a skilled artisan at the time of invention would have had any reason to believe plasmids would not elute from FTA® medium.

Thus, the rejection<sup>is</sup> maintained.

### ***Conclusion***

**Claim(s) 26, 27, and 33-48 are rejected. No claims are allowed.**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher M. Babic whose telephone number is 571-272-8507. The examiner can normally be reached on Monday-Friday 7:00AM to 4:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 571-272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.


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 1/8/08

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1/16/08